

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

23 MAY 2006

WIPO

PCT

Applicant's or agent's file reference 12562600/EJH/HPM/DYS	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/AU2005/000120	International filing date ( <i>day/month/year</i> ) 1 February 2005	Priority date ( <i>day/month/year</i> ) 3 February 2004	
International Patent Classification (IPC) or national classification and IPC  Int. Cl.  <i>A61K 31/4178 (2006.01) A61K 33/24 (2006.01) A61P 3/04 (2006.01) A61K 33/00 (2006.01)</i> <i>A61P 1/14 (2006.01)</i>			
Applicant AGT BIOSCIENCES LIMITED et al			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 7 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 2 December 2005	Date of completion of this report 05 May 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  JENNIFER FERNANCE Telephone No. (02) 6283 2269

**Box No. I**      **Basis of the report**

1. With regard to the language, this report is based on:

☒ The international application in the language in which it was filed☐ A translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:☐ international search (under Rules 12.3(a) and 23.1 (b))☐ publication of the international application (under Rule 12.4(a))☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:☐ the international application as originally filed/furnished☒ the description:

pages 1-62 as originally filed/furnished

pages\* received by this Authority on \_\_\_\_\_ with the letter of

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☒ the claims:

pages as originally filed/furnished

pages\* as amended (together with any statement) under Article 19

pages\* 63-69 received by this Authority on 21 April 2006 with the letter of 21 April 2006

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☐ the drawings:

pages as originally filed/furnished

pages\* received by this Authority on \_\_\_\_\_ with the letter of

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☐ claims Nos:

because:

☐ the said international application, or the said claims Nos.

relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.  
are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. **18-31**  
are so inadequately supported by the description that no meaningful opinion could be formed (*specify*)

☒ no international search report has been established for said claim Nos. **18-31**

☐ A meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ Furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ Furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ Pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ A meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

10/5885/6

IAP11 Rec'd PCT/PTO 03 AUG 2006

## 1. Statement

Novelty (N)	Claims 1-17, 32-35	YES
	Claims -	NO
Inventive step (IS)	Claims -	YES
	Claims 1-17, 32-35	NO
Industrial applicability (IA)	Claims 1-17, 32-35	YES
	Claims -	NO

## 2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: Ahern	D4: Sigma Catalogue
D2: Montell et al	D5: Gomez et al
D3: BIOMOL	

Novelty (N) Claims 1-17, 32-35

Claims 1-17 and 32-35 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose the use of ligands to the defined receptors to modulate the feeling of satiety. Therefore the subject matter of these claims is new and meets the requirements of Article 33(2) PCT with regard to novelty.

Inventive Step (IS) Claims 1-17 and 32-35

D1 discloses agents that are TRPV1 ligands and their activity in the modulation of satiety. D5 discloses that CB1 receptor agonists and antagonists modify satiety through the activity of TRPV1. TRPV-1 is a member of the TRPV group of cation channels. Thus the Person Skilled in the Art (PSA) would investigate the inhibition of related TRPV cation channels (such as TRPV2) and be led to the invention as presently claimed. Such an investigation would include the use of available blockers, promoters, agonists and antagonists of the receptors and/or direct modification of their genes. The PSA would also investigate the role of other TRPV channels in the role of satiety including gastric distension. Thus the PSA would be led to the invention as presently defined in claims 1-17 and 32-35 in light of D1 or D5.

D2 discloses the members of the TRP channel family including those presently claimed. Therefore D3 in combination with D1 or D5 deprive claims 1-17 and 32-35 of inventive step.

D3 and D4 disclose the commercially available SKF 96365 as a calcium ion channel modulator. Therefore D3 or D4 in combination with D1 or D5 deprive the claims 1-17 and 32-35 of inventive step.

(Continued in Supplemental Box)

**Box No. VIII** Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The claims are not limited to selective agonists or antagonists of the defined mechanoreceptors. The limitation that the agent be directed towards TRPV2 is not seen as a true limitation in that the exemplified ruthenium red is also a known TRPV1 antagonist while SK&F 96365 has not been demonstrated to be a selective TRPV2 antagonist. As TRPV1 is also known to influence satiety (see novelty citations), the selectivity of SK&F 96365 for TRPV2 should be fully supported. The discovery that TRPV2 is involved in gastric distension may be of interest but does not confer novelty or inventiveness on known treatments.

Therefore, the claims are not fully supported by the description. There is no support for :

- the use of any agent that is a selective agonist/antagonist for each or any of the defined mechanoreceptors (the exemplified agents are not selective);
- the use of any agent that is an agonist/antagonist of the defined receptors which are not ligands for the TRPV1 receptors; or
- the use of any agent that inhibits or enhances the expression of the defined genes.